

University of Dundee

Audit of eliminating biopsy for presumed fibroadenomas with benign ultrasound greyscale and shear-wave elastography findings in women aged 25–39 years

Evans, A.; Sim, Y. T.; Lawson, B.; Whelehan, P.

Published in:
Clinical Radiology

DOI:
[10.1016/j.crad.2020.08.002](https://doi.org/10.1016/j.crad.2020.08.002)

Publication date:
2020

Licence:
CC BY-NC-ND

Document Version
Peer reviewed version

[Link to publication in Discovery Research Portal](#)

Citation for published version (APA):

Evans, A., Sim, Y. T., Lawson, B., & Whelehan, P. (2020). Audit of eliminating biopsy for presumed fibroadenomas with benign ultrasound greyscale and shear-wave elastography findings in women aged 25–39 years. *Clinical Radiology*, 75(11), 880.e1-880.e3. <https://doi.org/10.1016/j.crad.2020.08.002>

General rights

Copyright and moral rights for the publications made accessible in Discovery Research Portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from Discovery Research Portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain.
- You may freely distribute the URL identifying the publication in the public portal.

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Audit of eliminating biopsy for presumed fibroadenomas with benign ultrasound greyscale and shear wave elastography findings in women aged 25-39 years

Key words

Breast, Ultrasound, shear wave elastography, fibroadenoma

Introduction

Fibroadenomas account for approximately 40% of breast biopsies performed around the world (1-3). The performance of these biopsies, pathological processing, pathological interpretation and discussion of the results is a large part of the workload of breast clinics.

The different ultrasound (US) features of breast cancer and fibroadenomas are well known (4,5) and the sensitivity of US for the detection of breast cancer is around 95%. Studies have shown that the sensitivity and specificity of ultrasound is statistically significantly greater than mammography in patients with breast symptoms for the detection of breast cancer and benign lesions particularly in dense breast and in young women (6). However, US of triple-negative (TN) cancers poses a particular problem as they often show benign US features such as distal enhancement and a well-defined margin (7,8). This problem is compounded by the young age distribution of TN breast cancer, which likely means that the pre-test probability of malignancy is relatively low. However, given the very low cancer incidence in women under 25 years old, many centres are now routinely using US features alone to determine when breast masses are benign (9,10). Some centres have also increased this age threshold to 30 years.

Shear wave elastography (SWE) is an US technique which measures tissue stiffness quantitatively and reproducibly. It has a similar sensitivity for invasive breast cancer as greyscale US (11). It takes about two minutes to perform and two minutes to extract the quantitative readings per case. The small proportion of cancers with benign SWE values tend to be small, screen-detected and low-grade (12). Such cancers are, however, rarely missed or misclassified by greyscale US. This means that SWE and greyscale US are complementary when used in combination to assess breast masses, with greyscale US missing some high-grade lesions and SWE some low-grade cancers. This is especially true when assessing women with symptoms, where small, low-grade cancers are less common. In a series of almost 700 symptomatic solid lumps, none of the cancers showed both benign greyscale US features and benign SWE features (13). A particular advantage of SWE is that its sensitivity for the detection of lobular cancer is similar to that for ductal (no-special-type) cancers (14). This is in contrast to all other routine breast imaging modalities.

Because of the above studies, our centre adopted a policy of not biopsying or following up symptomatic, clinically benign masses with benign greyscale US and SWE findings in women under 40 years of age. This policy was adopted in 2017. The aim of this study was to assess the outcomes of this policy in women aged 25-39 years, where a minimum of 12 months' follow-up data is available.

Methods

Patients were included after attending a one-stop clinic for women referred from their family doctor with breast symptoms. All patients complaining of a breast lump routinely have a focussed breast ultrasound scan with SWE examination of any solid mass seen on ultrasound. Four SWE images are obtained in two orthogonal planes and quantitative data obtained using a 2mm region of interest (ROI). Patients aged 25-39 with lesions showing benign US and clinical features and SWE findings below the threshold value (50 kPa average mean stiffness from the four SWE images) were reassured and discharged from the clinic without biopsy or follow-up. Mammography was not

performed as the patients were under 40 years and did not have suspicious clinical or US findings. Patients managed in this way had their details recorded on a dedicated audit form for review by a second radiologist. The single reviewing radiologist, an internationally recognised expert with 25 years specialist experience in breast imaging, checked that the lesion did have definitively benign US features. If the second radiologist did not agree with the benign US designation, the patient was recalled for repeat US and possible core biopsy.

Patients managed in this way before 01/05/2019 were included in this audit. Local electronic records were viewed to establish whether patients re-presented with the same or different benign breast problems, developed breast cancer, or had further diagnostic biopsies. If local records did not show recent attendance, then the national picture archiving and communication system (PACS) was accessed to identify any subsequent breast imaging anywhere in the NHS in the devolved UK nation that was the setting for this study.

Rates of recall and re-assessment review of stored US images by the second radiologist were documented. Similarly, rates of re-presentation with the same benign lesion, other benign problems and breast cancer were calculated.

Results

Seventy-six consecutive patients were eligible for the audit. The age range was 25-39 years with a mean age of 33 years. The minimum follow-up was 12 months. Average follow-up was 2 years. One patient was excluded as she died of non-breast causes two weeks after attending the clinic, leaving 75 women in the cohort.

Three (4%) patients were recalled after review of the US images by the second radiologist. Two were discharged following a second US scan while one underwent a core biopsy with a benign result. Five (7%) patients re-presented with the same lump, two of those had a core biopsy at this second presentation because of enlargement of the lesion, with benign results. Three women had a similar

sized lump as at initial presentation and were further reassured and discharged. None of the five patients who re-presented had a surgical excision of the lump. Three (4%) patients presented with a different benign problem during follow-up.

Two patients presented with breast cancer, both in the ipsilateral breast. In neither patient was the cancer in the same area as the previously assessed benign lump. In both cases, imaging including MRI scan confirmed the cancers as separate from the previously assessed benign lesions.

None of the women in the study cohort presented to other NHS breast units in the country and had breast imaging recorded on PACS during the follow-up period.

The number of women aged 25-39 who had symptomatic clinically benign masses with benign core biopsy results who were biopsied because of atypical US appearances or stiffness at SWE was not recorded.

Discussion

We have found that a policy of not biopsying or following up symptomatic, clinically benign solid breast masses with benign US and SWE features appears safe so far, as no cancers were diagnosed at follow-up in the area of the previously assessed benign masses. There was good consensus among the radiologists regarding the benign US findings as only 4% were recalled for reassessment after review of the stored US images by the second radiologist, and all such reassessments had a benign outcome. Only 7% of patients re-presented with the same lump and these episodes resulted in two core biopsies but no surgical excisions. The lack of surgical excisions may imply that the patients on the new pathway were adequately reassured.

The number of women aged 25-39 years who had their clinically benign masses biopsied during the study period because of either non-benign US greyscale features or above-threshold stiffness at SWE was not recorded. It is therefore not possible to say what percentage of women with benign symptomatic masses in this age group avoided core biopsy due to adoption of this policy.

It is estimated that 10% of all women have a fibroadenoma (15) and that about 40% of breast biopsies are from fibroadenomas (1-3). The burden of work caused by fibroadenomas is therefore difficult to overstate. Given the greater and increasing complexity of radiological workup of cancer cases, any decrease in work from benign problems will enable breast radiologists to give more time to imaging of cancer cases.

The follow-up of an average of two years in this study is short and it is possible that missed cancers may yet appear. Therefore, these results can only be interpreted as promising rather than as definitive evidence of the safety of this approach. However, most re-presentations of an undiagnosed but already symptomatic cancer occur within two years (16). Only 7% of cancers occurring as “interval cancers” after assessment at one-stop symptomatic clinics occur in women aged under 40; therefore, reducing diagnostic interventions in this age group would appear not be a high-risk strategy (16).

A further limitation of this study is that it is a small sample from a single centre with an academic interest in SWE. However, SWE is a simple, reproducible technique so it would be surprising if these results could not be replicated by other centres. SWE is also a quick, relatively low-cost procedure, so its introduction into the standard workflow of any breast clinic should not present problems.

The adoption of this approach by other centres is only recommended after individual centres assess a cohort of patients to confirm that no cancers are missed by both SWE and US, while continuing to biopsy clinically benign masses with benign US and SWE features in the age-group concerned. The majority of cancers missed by SWE are small (11), so some may wish to adopt this approach for lesions over 10mm in size only.

As follow-up and biopsy of benign masses constitutes a large part of breast radiologists’ workload, in health care systems where a fee-per-item model exists there may be concerns about resultant decrease in income.

Extending the age limit for this policy to 49 years could be contemplated after longer follow-up of a larger numbers of patients. However, it should be noted that women aged 40-49 are those most likely to have a cancer presenting following a one stop clinic negative assessment (15) so such an approach should be considered cautiously.

In conclusion, early results of a policy of not biopsying or following up benign solid masses with benign US appearances, which are soft on SWE, in women aged 25-39 suggest this approach may be safe and acceptable. Data on larger cohorts from multiple centres with longer follow-up are required to confirm this early promise.

References

1. Uwaezuoke SC, Udoeye EP. Benign breast lesions in Bayelsa State, Niger Delta Nigeria: a 5 year multicentre histopathological audit. Pan African Medical Journal. 2014; 19:394
doi:10.11604/pamj.2014.19.394.5717
2. Bewtra C. Fibroadenoma in women in Ghana. Pan African Medical Journal. Year 2009 Volume 2: Issue 11
3. Albasri AM, Profile of benign breast diseases in western Saudi Arabia. An 8-year histopathological review of 603 cases. Saudi Med J 2014; 35:1515-1520
4. Costantini M, Belli P, Lombardi R, et al. Characterization of Solid Breast Masses: Use of the Sonographic Breast Imaging Reporting and Data System Lexicon. J Ultrasound Med 2006 May;25:649-59
5. Hong AS, Rosen EL, Soo MS, Baker JA. BI-RADS for Sonography: Positive and Negative Predictive Values of Sonographic Features. Am J Roentgenol 2005 Apr;184:1260-5

143 6. Devolli-Disha E, Manxhuka-Kërliu S, Ymeri H, Kutllovci A. Comparative accuracy of mammography
 144 and ultrasound in women with breast symptoms according to age and breast density. *Bosn J Basic*
 145 *Med Sci.* 2009;9:131-136. doi:10.17305/bjbms.2009.2832

146 7. Du H-Y, Lin B-R, Huang D-P Ultrasonographic findings of triple-negative breast cancer. *Int J Clin Exp*
 147 *Med* 2015;8:10040–10043

148 8. Wojcinski S, Soliman AA, Schmidt J, et al Sonographic features of triple-negative and non-triple-
 149 negative breast cancer. *J Ultrasound Med* 2012;31:1531–1541

150 9. Maxwell AJ, Pearson JM. Criteria for the Safe Avoidance of Needle Sampling in Young Women
 151 With Solid Breast Masses. *Clin Radiol.* 2010; 65:218-22

152 10. Smith GEC, Burrows P. Ultrasound Diagnosis of Fibroadenoma - Is Biopsy Always Necessary? *Clin*
 153 *Radiol.* 2008 ;63:511-5

154 11. Evans A, Whelehan P, Thomson K, Brauer K, Jordan L, Purdie C, McLean D, Baker L, Vinnicombe S,
 155 Thompson A Differentiating benign from malignant solid breast masses: value of shear wave
 156 elastography according to lesion stiffness combined with gray scale ultrasound according to BI-RADS
 157 classification. *Br J Cancer.* 2012 Jul 10;107(2):224-9

158 12. Vinnicombe S, Whelehan P, Thomson K McLean D, Purdie CA, Jordan LB, Hubbard S, Evans A.
 159 What are the characteristics of breast cancers misclassified as benign by quantitative ultrasound
 160 shear wave elastography? *European Radiology* 2014 Apr;24(4):921-6

161 13. Giannotti E, Vinnicombe S, Thomson K, McLean D, Purdie C, Lee J, Evans A. Shear wave
 162 elastography and grey scale assessment of palpable probably benign masses: is biopsy always
 163 required? *Br J Radiol.* June 2016; 89(1062): 20150865

164 14. Sim YT, Vinnicombe S, Whelehan P, Thomson K, Evans A. Value of shear-wave elastography in the
 165 diagnosis of symptomatic invasive lobular breast cancer. *Clin Radiol* 2015;70:604-609

- 166 15. Hughes LE, Mansel RE, Webster DJT, Gravelle IH. Benign disorders and diseases of the breast:
167 concepts and clinical management. London: Baillière Tindall; 1989
- 168 16. Britton P, Duffy SW, Sinnatamby, Wallis M, et al. One stop diagnostic breast clinics: how often
169 are breast cancers missed? Br J Cancer 2009;100:1873-1878
- 170
- 171